

## **REMARKS**

### **I. Claim Rejections - §102**

Claims 1 and 19 are rejected as being anticipated by the Sharma et al. publication 2004/0106956.

Sharma is directed to an IMD that discriminates between a ventricular tachycardia (VT) and a supraventricular tachycardia (SVT) in order to determine whether to delivery a subsequent therapy. According to Sharma, after ATP is delivered, the system monitors the time before an intrinsic heart beat is sensed. If the time is longer than a predetermined time window, the tachycardia is classified as a SVT. The premise is that the ATP would place the AV node in a refractory condition and only an intrinsic heart beat originating in the ventricle would be sensed within the window because the pulse does not have to travel through the AV node. See paragraph [0022].

The methodology of discrimination and subsequent therapy delivery is set forth in the flowchart of Fig. 4 as follows:

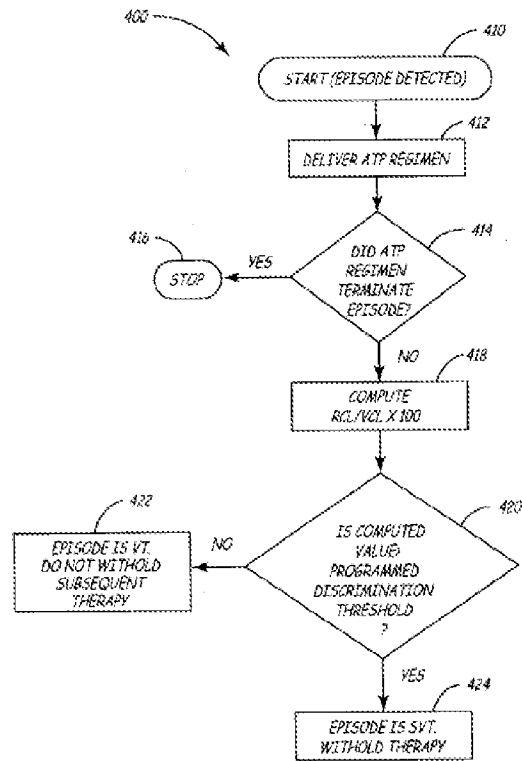


FIG. 4

As shown there, when a tachyarrhythmia episode is detected, an ATP regimen is delivered. Once delivery of the ATP is completed, the normalized RCL is computed at 418, which corresponds to T3 in Figs. 3A and 3B. Then T3 is compared to the programmed threshold to determine if T3 is greater. If T3 is not greater, as in Fig. 3A, the event is determined to be a VT. If T3 is greater, as in Fig. 3B, the event is determined to be a SVT.

Applicant previously pointed out that Sharma fails to disclose delivery of an exploratory ATP, measuring the exploratory ATP Return Cycle Length (RCL), formulating an ATP regimen having ATP parameters defined as a function of a measured exploratory RCL and delivering the formulated ATP regimen to the heart chamber. The examiner responded that “formulating” can mean to

determine whether to apply a particular ATP regimen, even if the ATP regimen is not new or modified.

In the Advisory Office Action, the examiner further explains that the basis for the rejection is the construction of the claim language such that “parameters of an anti-tachycardia pacing include the start time (i.e., the time that the first pacing pulse is delivered) of the pacing regimen.” See page 2. Also, the examiner explains an understanding of Sharma to be that the start-time of the ATP therapy differs depending upon whether the IMD determine that the episode is a VT or a SVT. Based upon the claim construction and the understanding of Sharma, the conclusion is made that Sharma anticipates the claimed invention.

Applicants respectfully assert that the construction erroneously includes operational aspects of the IMD that are outside the sequence of pacing pulses of the ATP regimen. That is, the start-time of therapy delivery is a parameter of the IMD operation and is formulated by the IMD as a parameter of the therapy delivery. The ATP regimen parameters are aspects of the actual sequence of pacing pulses being delivered. Further, what is identified in Sharma is a determination as to whether a subsequent therapy is delivered or not. That is merely a “go” / “no go” decision on therapy delivery. A mere “on-off” switch is not a parameter of an ATP regimen. As set forth in Sharma at paragraph [0066], Fig. 4 is the functional operation of the discrimination of arrhythmias. As pointed out in paragraphs [0066] through [0068], the logic flow chart 400 of Fig. 4 relates to the operation of the IMD as a whole in regard to discriminating between VT and SVT for subsequent therapy delivery purposes. The rejection is, therefore, in error.

In order to expedite allowance of the present application, Applicant has amended claim 1 to further specify in the independent claims that the ATP regimen that is formulated has ATP cycle length parameters that are defined as a function of the measured exploratory RCL. Regardless of how “formulating” is construed, Sharma does not disclose any therapy, whether delivered or not,

wherein the ATP cycle length is defined as a function of the measured exploratory RCL.

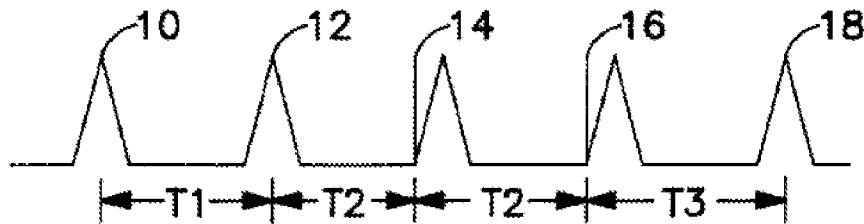
Thus, the Sharma publication does not anticipate and the rejection should be withdrawn.

Claims 1 and 19 are also rejected as being anticipated by DeGroot (US 6,167,308).

DeGroot discloses a tiered therapy device wherein ATP therapy is first delivered and, if there is no increase in the RCL, the next scheduled therapy is delivered, which is either a new ATP regimen with different parameters or a high energy cardioversion shock. Applicant advanced the argument that DeGroot does not anticipate because the device does not formulate a new ATP regimen having ATP parameters defined as a function of the measured exploratory RCL.

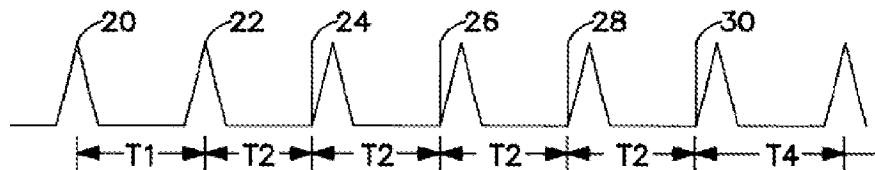
The examiner again responded that the broadest interpretation of “formulate” includes selection of which ATP regimen to apply regardless of how the ATP parameters are defined. According to the examiner, because DeGroot selects which ATP regimen to apply based on measured RCL, the IMD is considered to “formulate an ATP regimen as a function of the measured RCL.” However, claims 1 and 19 set forth the ATP parameters of an ATP regimen are defined as a function of the measured exploratory RCL. This is absent in DeGroot. The claims do not merely specify that a different ATP therapy regimen is invoked based upon the measurement of the RCL of the preceding ATP therapy regimen. In order to make this even clearer, claims 1 and 19 are being amended to further specify that the cycle length of the formulated ATP regimen is itself formulated as a function of the measured exploratory RCL.

As was pointed out previously, in contrast to the present invention, DeGroot has no exploratory ATP regimen. DeGroot begins with a first ATP therapy regimen having pulses separated by T2, which is a function of the duration of the intervals T1 between the preceding R-waves during the tachycardia as shown in Fig. 1. See col. 2, lines 43-52.



**FIG. 1**

The first ATP therapy regimen with T2 pulses is suspended and the return cycle length T3 is measured. The first ATP therapy regimen with T2 pulses is resumed and then again suspended to measure the RCL (T4). See Fig. 2.



**FIG. 2**

The RCL of T4 is then compared to the RCL of T3. If T4 is not greater than T3, then a new ATP regimen having an inter-pulse interval somewhat less than T2 is initiated. See col. 2, line 66 to col. 3, line 3. Thus, in DeGroot, as to any new or modified second ATP therapy regimen that is initiated, the ATP parameters (e.g., the inter-pulse interval) are established as a function of the interval T2, which in turn is established as a function of the tachycardia interval T1. The ATP parameters are not a function of the measured RCL of an exploratory ATP regimen. And, even if the first ATP therapy regimen in DeGroot is characterized as being an “exploratory” ATP regimen, it remains that according to DeGroot, the inter-pulse interval of any subsequent ATP therapy regimen is established as a function of the interval T2 of the first AT therapy regimen and not the measured interval T3 or T4.

Thus, DeGroot does not anticipate and the rejection should be withdrawn.

## **II. Claim Rejections - §103**

Claims 2-18 and 20-38 are rejected as being obvious from DeGroot in view of Sun et al. (US 6,400,986). The rejection is premised on DeGroot teaching to formulate an ATP regimen having ATP parameters defined as a function of a measured exploratory RCL. As discussed above, that characterization of DeGroot is in error; and in any event, DeGroot is now distinguished by reason of the amendments to claims 1 and 19 . Accordingly, the obviousness rejection of claims 2-18 and 20-38 should be withdrawn.

## **III. Conclusion**

Applicant submits that all claims are patentable over the prior art cited and that the application is in condition for allowance. An early action to that effect is courteously solicited.

Respectfully submitted,

July 20, 2006  
Date

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